K062054

510(k) Summary

as required by 807.92

OCT - 6 2006

1. Company Identification

EIZO NANAO CORPORATION
153 Shimokashiwano-cho, Hakusan, Ishikawa-ken, 924-8566, Japan
Tel: +81-76-274-2468
Fax: +81-76-274-2484

2. Official Correspondent

Hiroaki Hashimoto (Mr.)
Manager of Engineering Management Section

3. Date of Submission

July 3, 2006

4. Device Trade name

RadiForce GS510, 5 Megapixel Monochrome LCD Monitor

5. Common/Usual Name:

Image display system, medical image workstation, image monitor/display, and others

6. Classification Number:

Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer	:	EIZO NANAO CORPORATION
Device Name	:	5 Megapixel Monochrome LCD Monitor
Model Name	:	RadiForce G51
510(k) No.	:	K042755

8. Description of Device

RadiForce GS510 device is a digital image display. G51 displays high-definition (5 Megapixel) medical imaging.

9. Intended Use

RadiForce GS510 is intended to be used in various kinds of medical image applications including digital mammography system for which the device complies with the performance specified by the manufacturer of the system.

10. Substantial Equivalence to Predicate Device

RadiForce GS510 is substantially equivalent to G51. GS510 employs the maximum resolution values same as that of G51. Additional product innovations include Digital Uniformity Equalizer (DUE), which enables compensates for luminance non-uniformity. Comparison table of the principal characteristics of 2 devices is shown in the Attachment 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT - 6 2006

Eizo Nanao Corporation
c/o Koji Kubo
Medical Device Division
Cosmos Corporation
319 Akeno, Obata-cho
Ise-shi, Mie-ken, 519-0501
JAPAN

Re: K062054
Trade/Device Name: 5 Megapixel Monochrome LCD Monitor, RadiForce GS510
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 4, 2006
Received: September 8, 2006

Dear Mr. Kubo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

July 13, 2006

Indications for Use

510(k) Number (if known): K062054

Device Name: RadiForce GS510

Indications For Use:

RadiForce GS510 is intended to be used in various kinds of medical image applications including digital mammography system for which the device complies with the performance specified by the manufacturer of the system.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062054